REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which are believed to place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 24-26, 30-32 and 34-42 are pending in this application. Claims 24-26, 30-32 and 34-36 are amended; claims 37-42 are added. Claims 24 and 30 have been made independent, incorporating the limitations formerly found in cancelled claims 23 and 29. Support for the amended claims is found throughout the specification.

Specifically, support for "100 to 300 nucleotides" in claims 24 and 36 can be found on page 17, line 2.

Support for the recitation of "16 consecutive nucleotides" in claims 24, 26, 30, 34-36, 39, 41 and 42, and for the recitation of "20-24 consecutive nucleotides" in claims 37 and 40 can be found in the amended paragraph beginning on page 16, line15. Support for the amendment to the specification can be found in the first paragraph on page 14.2 and in the first paragraph on page 14.15 of Sambrook *et al.*, 1989, which is incorporated by reference into the present application. (See page 1, line 15, of the application for incorporation by reference, and page 22, lines 17-20, which states that all recombinant DNA techniques are carried out according to standard protocols as described in Sambrook *et al.*) For the Examiner's convenience, a copy of Chapter 14 of Sambrook *et al.* is attached.

The remaining amendments are made to place the claims in better form and to round out the scope of protection to which Applicants are entitled. No new matter is added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE REJECTIONS UNDER 35 U.S.C. §112, 1ST PARAGRAPH ARE OVERCOME

Enablement

Claims 23-26, 29-32 and 34-36 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

In making this rejection, the Office Action states that not all probes and primers can be used in PCR and Southern analysis and that the specification only describes 9 primers (SEQ ID Nos:4-7, 9 and 11-14) that function in the invention. The Office Action goes on to say that the extent to which the primers "hybridize" is not clear and that the claimed sequences would encompass approximately 6300 20-base long primers that have exact complementarity to the claimed sequences and multitudes of other lengths and/or that have mismatches. The Office Action further states that "the specification must describe primers within the full scope of the claimed invention" and that "the sequences of the primers are not described within the full scope of the claimed invention".

All claims have been amended to recite that the specific PCR probes or primers comprise at least 16 or 20 to 24 consecutive nucleotides from either the foreign DNA (SEQ ID NO:1), the 5' flanking region (SEQ ID NO:8) or the 3' flanking region (SEQ ID NO:10) of MS-B2, or the respective complements thereof. Therefore, each of the foreign DNA, the 5' flanking region and the 3' flanking region are characterized by a specific nucleotide sequence, set forth in sequence listing entries SEQ ID NO:1, comprising SEQ ID NO:12 and SEQ ID NO:8, and SEQ ID NO:10, comprising SEQ ID NO:11, respectively. Further, in the claims, the sequences of the 5' and 3' flanking sequences have been specifically delimitated to the nucleotide sequences of plant origin, *i.e.* the nucleotides from position 1 to 234 of SEQ ID NO:8, and from position 194 to 416 of SEQ ID NO:10, comprising SEQ ID NO:11. Throughout the present application, the exemplified oligonucleotides (*e.g.* MDB355 and MLD008 on page 30; MDB371, MDB201, CVZ7 and CVZ8 on page 38) used for PCR amplification are at least 16 or 20 to 24 nucleotides in length. It is respectfully submitted that a person skilled in the art would, based on standard protocols for PCR amplification (as *e.g.* described in Chapter 14 of Sambrook et al., 1989; enclosed), use oligonucleotides, which are at least 16 or 20 to 24 nucleotides in length, for priming the PCR, and could perfectly well envision each and every primer or probe encompassed by the current claim language. In fact, computer-assisted primer design programs are available,

such as PRIMER DESIGN®, wherein the nucleotide sequence to be amplified can be scanned by a "window" adjustable in nucleotide length, to generate each and every possible primer.

Furthermore, the current claims no longer contain hybridization language, and are directed to primers or probes which comprise at least 16 or 20 to 24 consecutive nucleotides selected from the nucleotide sequence of the foreign DNA in SEQ ID NO:1, from the nucleotide sequence of the 3' flanking region comprised in SEQ ID NO:10, from the nucleotide sequence of the 5' flanking region comprised in SEQ ID NO:8, or the complement of these sequences. Furthermore, the primers are explicitly limited to those specific regions of SEQ ID NO: 8 and 10 of plant origin, *i.e.* from the nucleotides from position 1 to 234 of SEQ ID NO:8, and from position 194 to 416 of SEQ ID NO:10.

According to the Court of Appeals for the Federal Circuit in the case of *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988):

> Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. **The key word is undue, not experimentation.** The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. **The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed** ... [Emphasis added. Citations omitted].

Id. at 1404.

Against this background, determining whether undue experimentation is required to practice a claimed invention turns on weighing many factors summarized in *In re Wands* (*Id.*), for example, (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

Applying *Wands* to the instant facts, enablement is shown to exist. The amount of direction or guidance presented is high; the specific sequences from which the primer or probe is to be selected and the length of the primer or probe is taught by the specification and recited in

the claims. Working examples are present and several different primers are used in PCR amplification of foreign MS-B2 in the examples. The development of PCR primers or probes is routine; the relative skill of those in the art is high; and the predictability of the art is also high. The fact that some experimentation may be required to determine whether a particular primer set will amplify the desired elite event MS-B2 DNA does not lead to the conclusion that the experimentation is undue. No evidence to the contrary has been presented.

Further, Applicants should not be limited to only the primers used in the Examples of the application. As stated in MPEP 2164.02, "[p]roof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation." Again, such evidence has not been provided here.

It is respectfully submitted that each species is structurally defined by its length (at least 16 or 20 to 24 nucleotides) and its sequence (at least 16 or 20 to 24 consecutive nucleotides selected from three specific sequences or their complement), and that the skilled artisan can practice the claimed invention without undue experimentation using the specification and his or her knowledge of the art.

Written Description

Claims 23-26, 29-32 and 34-36 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. The rejection is traversed.

As explained above, the specification describes primers or probes selected from specific sequences. While the Examiner points out that not all probes and primers are ideal for PCR, primer design is a well-established art, and the skilled artisan would clearly be able to envision primers of a specified length (16 or 20-24 consecutive nucleotides), selected from a specified sequence.

Applicants need not have physical possession of each and every primer and probe encompassed by the claims, as these can be readily determined by those skilled in the art. Applicants maintain that each and every primer and probe encompassed by the claims could be written out by one skilled in the art with only the specification as a reference and could be generated and used in the claimed method. Further, the structural features that distinguish the encompassed primers and probes from other nucleic acids are clearly delimited by the

requirement that the primers or probes are drawn from bases 1-234 of SEQ ID NO:8, bases 194-416 of SEQ ID NO:10, SEQ ID NO:1, or the complement of these sequences.

Applicants maintain that the sequences of the primers are described within the full scope of the invention. It is further maintained that a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, and structural features common to the genus have been disclosed. A list of primers and their sequence identifiers can be found, for example, on page 23 of the specification.

In view of the amendments and arguments submitted herein, reconsideration and withdrawal of the §112, first paragraph, rejections are requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112, 2ND PARAGRAPH ARE OVERCOME

Claims 23-26, 29-32 and 34-36 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejections are traversed.

The claims no longer recite "hybridizes", overcoming the rejections on this basis.

Claim 36 more clearly defines that steps of "using a polymerase chain reaction".

In claim 24, the recitation of "between 160 and 200 by from a nucleic acid" in line 2 was intended to read --bp--; however, this phrase has been removed entirely, obviating the rejection.

Claims 25 and 30 were rejected as being unclear. Claim 25 now refers to "said second specific primer or probe" of claim 24 and claim 30 describes both "a first and a second PCR primer or probe".

The Office Action states that it is unclear in Claim 34 where samples of seed lots come into the method. As amended, claim 34 clarifies the wording, such that the MS-B2 specific region is detected "in said seeds".

The Office Action asserts that Claim 35 is indefinite for failing to recite in what one carries out PCR or Southern blot. Claim 35 has been amended to recite that PCR is carried out "in the genomic DNA of seeds".

Reconsideration and withdrawal of the rejections under §112, second paragraph, are requested.